

REMARKS

Claims 12-49 are pending. Claims 1-11, 23, 31, 38, and 43 have been canceled. Claims 12-16, 18, 22, 37, 39-42, 44-46, and 49 have been amended. Claims 12-16, 18, 37, 39-42, 44-46, and 49 have been amended to overcome the rejection under 35 U.S.C. § 112, sixth paragraph. In addition, claims 13, 22, and 37 have been amended to include similar elements to the elements in claim 12. No new matter is added. Reconsideration of the application and withdrawal of rejections are respectfully requested.

The office communication with notification date of August 29, 2012 is referred to as "Office Action" hereinafter.

§ 112 Rejections

Claims 12-21 and 37-49 are rejected under 35 U.S.C. §112, sixth paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention. Applicants respectfully traverse this rejection; however, to further this application toward allowance, Applicants have made amendment to the claims.

Claims 12-16, 18, 37, 39-42, 44-46, and 49 have been amended to overcome the rejection under 35 U.S.C. §112, sixth paragraph. Applicants submit that the rejection of claims 12-21 and 37, 39-42, 44-49 under 35 USC § 112, second paragraph, has been overcome, and that the rejection should be withdrawn.

§ 103 Rejections

Claims 12-22 and 26-49 are rejected under 35 USC § 103(a) as being unpatentable over Mangram et al., "Guideline for Prevention of Surgical Site Infection" (hereinafter "Guidelines") in view of Ormond-Walshe, Sarah, "Computerized Databases in Infection Control" (herein after "Walshe"), and further in view of US Patent No. 6,157,853 to Blume and in even further view of US Patent No. 5,562,448 to Mushabac, and in even further view of US Patent Application Publication 2002/0077865 to Sullivan and in even further view of US Patent No. 6,509,730 to Afsah. Claims 23-25 are rejected under 35 USC § 103(a) as being unpatentable over in view of Ormond-Walshe in view of Blume and in further view of Mushabac and in further view of

Sullivan and in further view of Afsah, and in even further view of U.S. Patent Number 6,662,081 to Jacober.

The Patent Office recognized that the combination of Guidelines and Ormond-Walshe failed to disclose or suggest identifying when the data indicative of the practice associated with the surgical procedure is not in compliance with a rule, as required by independent claims 12, 13, 22, and 37. However, the Patent Office stated that this feature is well known in the art as evidenced by Blume and Mushabac.

The entire passage of Blume relied upon by the Patent Office is reproduced below:

Data received from localizers 20, and the processing by processor 32 to present a graphical representation on display 40 of the magnetic field produced by magnet 14 must be fast enough to provide "real-time" feedback for a surgeon; i.e., the feedback must be rapid enough to allow decisions to be made during a surgical procedure involving the movement of the implanted magnetic device 30. The method of Procrustes is used to compute the 4.times.4 rigid body transformation between coordinates in the imaging system and coordinates in the localizer system. Thereafter, the 4.times.4 matrix may be applied to transform a pre-stored representation of a magnetic field into a magnetic field having the position and orientation sensed by localizers 20 using standard programming techniques on a presently-available Intel PENTIUM.RTM.-based processor (such as a typical PC), or a Silicon Graphics workstation, with the transformation being accomplished in sufficient time to provide a display that is updated rapidly enough for surgical purposes. Column 7, lines 16-33.

Contrary to the conclusion drawn in the Office Action, this teaching in Blume has no relevance with respect to the features recited in Appellant's claims, which concern computer-implemented systems for managing the risk or occurrence of surgical site infection. In contrast to Appellant's claims, the above passage of Blume describes the use of magnets in a surgical procedure to provide the surgeon with positioning feedback via a display regarding the positioning and movement of an implanted magnetic device. Thus, this teaching of Blume has no relevance to computer-implemented systems for managing the risk or occurrence of surgical site infection, and lacks any teaching pertinent to such endeavors.

Furthermore, the teaching of Blume cited above clearly lacks any suggestion of identifying when the data indicative of the practice associated with the surgical procedure is not in compliance with a rule established for the practice to thereby manage the risk of surgical site infection incident to the surgical procedure (claims 22 and 37) or generating a flag when a given

health care delivery practice associated with the surgical procedure is not in compliance with a rule to thereby manage the risk of surgical site infection incident to the surgical procedure (claims 12 and 13).

Similarly, the teaching of Mushabac relied upon in the Office Action is also irrelevant to the features of Appellant's claims. The relied upon passage of Mushabac is reproduced below.

Advantageously, the computer provides the dental practitioner operating the dental tool with an alert signal regarding deviation between an actual position and orientation of the tool during the use of the tool on the patient and the optimal position and the optimal orientation, as determined prior to the dental operation. The alert signal may take the form of an auditory signal, for example, a verbal message or instruction synthesized by the computer. Alternatively or additionally, the alert signal may include a visual indication provided on the monitor. An alert signal may also be provided in a practice operation, to indicate to the operator a deviation or a conformity of the practice instrument to the predetermined, recommended position and orientation thereof. Column 4, lines 56 to column 5, line 2.

This passage of Mushabac lacks any relevance to computer-implemented systems for managing the risk or occurrence of surgical site infection. Instead, this passage of Mushabac describes a dental tool that generates an audible or visible alert when the dental tool is mis-positioned.

An alert that is generated when a dental tool is mis-positioned is nothing akin to the features of Appellant's claims, e.g., identifying when the data indicative of the practice associated with the surgical procedure is not in compliance with a rule established for the practice to thereby manage the risk of surgical site infection incident to the surgical procedure (claims 22 and 37) or generating a flag when a given health care practice associated with the surgical procedure is not in compliance with a rule to thereby manage the risk of surgical site infection incident to the surgical procedure (claims 12 and 13). A person of ordinary skill in the art would not have had any rational reason to modify any computer-implemented system for managing the risk or occurrence of surgical site infection (e.g., per a combination of Guidelines and Ormond-Walshe) to generate a flag when a surgical procedure is not in compliance with a rule, or to identify when the data indicative of the practice associated with the surgical procedure is not in compliance with a rule established for the practice to thereby manage the risk of surgical site infection incident to the surgical procedure.

Indeed, the teachings of Blume and Mushabac are completely unrelated to those of Guidelines and Ormond-Walshe. Accordingly, a person of ordinary skill in the art would have found no reason to modify the teachings of Guidelines and Ormond-Walshe in view of Mushabac and Blume. To be sure, Blume describes a system that provides a surgeon with positioning feedback via a display regarding the positioning and movement of an implanted magnetic device, and Mushabac describes a dental tool that generates an alert when the tool is mis-positioned. These teachings concern totally different endeavors than those of Guidelines and Ormond-Walshe and include no teachings pertinent to the management of infection in surgical procedures.

Furthermore, even if the alert generation in Mushabac could be reasonably construed as generating a flag, the alert in Mushabac occurs when a dental tool becomes misaligned, and has no relevance to compliance of a surgical procedure with a rule, nor any relevance to the management of risks of surgical site infection incident to the surgical procedure.

In short, neither Mushabac nor Blume discloses or suggests computerized identification of data associated with a surgical procedure to thereby manage the risk of surgical site infection incident to the surgical procedure (claims 22 and 37) or computerized generation of a flag when a given health care practice associated with the surgical procedure is not in compliance with a rule to thereby manage the risk of surgical site infection incident to the surgical procedure (claims 12 and 13). For at least the reasons described above, a *prima facie* case of obviousness has not been established with respect to claims 12, 13, 22, and 37, and the rejection of claims 12, 13, 22, and 37 under 35 U.S.C. § 103(a) has been overcome and should be withdrawn.

Claims 2-14, 16-19, 21-24, and 25-32 add additional features to its respective base claim and are patentable for at least the same reasons.

All outstanding objections and rejections are believed to have been met and overcome. If a telephonic conference with Applicants' undersigned representative would be useful in advancing the prosecution of the present application, the Examiner is invited to contact the undersigned at (651) 575-3644. A notice of allowance for all pending claims is respectfully solicited.

Respectfully submitted,

December 11, 2012

Date

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